

PTO 1390 Page 1 of 1

US Dept. of Commerce Pat. & Trademark Office

Attorney's Docket No.

22054

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 USC 371

US. Application No. (if known)

09/980573

INTERNATIONAL APP. NO.
PCT/EP00/03997

INTERNATIONAL FILING DATE
4 May 2000

PRIORITY DATE CLAIMED
4 May 1999

TITLE OF INVENTION

DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN THE FOREHEAD AREA OF A PATIENT

APPLICANT(S) FOR DO/EO/US

Harald GINGER et al

Applicant herewith submits to the United States Designated/Elected Office (DO/EU/US) the following .

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 USC 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371.
3. ☐ This is an express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 317(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 USC 371(c)(2)).
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau.
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Patent Office.
6. ☒ A translation of the International application into English.
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau.
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3).
9. ☐ An oath or declaration of the inventor(s) (35 USC 371(c)(4).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).

Items 11. to 16. below concern documents or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An Assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items of information.
Drawing (4 sheets)

US Application no (if known)

09/98057

International Application no.

PCT/EP00/03997

JG13 Rec'd PCT/PTO 31 OCT 2001

Attorney's Docket No.

22054

17. The following fees are submitted:

Basic National Fee (37 CFR 1.492(a)(1)-(5)):

Search report has been prepared by the EPO or JP \$890.00

Int'l prel. exam. fee paid to USPTO (37 CFR 1.482) \$710.00

No int'l prel. exam. fee paid to USPTO (37 CFR 1.482)

but int'l search fee paid to USPTO (37 CFR 1.445(a)(2)) \$740.00

Neither int'l prel. exam fee (37 CFR 1.482) nor

int'l search fee (37 CFR 1.455(a)(2)) paid to USPTO \$1040.00

Intl. prel. exam. fee paid to USPTO (37 CFR 1.482)

and all claims satisfied provisions of PCT Art. 33(2-4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT

CALCULATIONS PTO USE ONLY

\$1,040

Surcharge of \$130.00 for furnishing oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS

NO. FILED

NO. EXTRA

RATE

Total claims

20

0

\$18

\$0

Ind. claims

4

1

\$84

\$84

MULTIPLE DEP. CLAIM(S) (if applicable) (see prel. amt.)

280

TOTAL OF ABOVE CALCULATIONS

\$1,124

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (37 CFR 1.2, 1.27, 1.28)

\$0

SUBTOTAL

\$1,124

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).

TOTAL NATIONAL FEE

\$1,124

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The Assignment may be accompanied by an appropriate PTO-1595 cover sheet (37 CFR 3.28, 3.39)

TOTAL FEES ENCLOSED

Amt to be refunded

Amt to be charged

- a. ☐ A check in the amount of \$ to cover the above fees is enclosed
- b. ☐ Please charge my deposit account 18-2025 \$ to cover the above fees. A copy of this sheet is enclosed.
- c. ☒ Please charge the amount due to the credit card identified in the attached PTO-2038.
- d. ☒ The commissioner is authorized to charge any additional fees which may be required or credit any overpayment to deposit account 18-2025. A copy of this sheet is enclosed
- e. A PTO-2038 in the amount of \$ to cover recordal of the Assignment is enclosed

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:

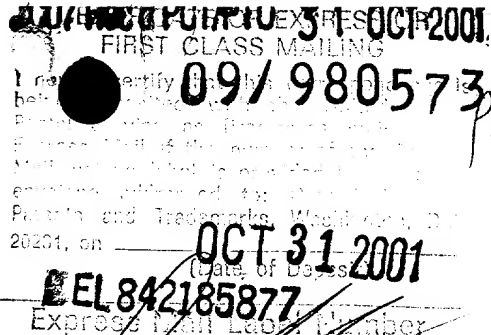
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22054



12-03-01



IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor Harald Genger et al
Patent App. Not known (US Nat'l phase of PCT/EP00/03997)
Filed Concurrently herewith
For DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN
THE FOREHEAD AREA OF A PATIENT

Hon. Commissioner of Patents
Washington, DC 20231

RECORD OF TRANSMITTAL--PCT APPLICATION

<input checked="" type="checkbox"/>	PCT Transmittal	
<input checked="" type="checkbox"/>	PCT Application	
<input checked="" type="checkbox"/>	Translation	
<input checked="" type="checkbox"/>	Sheets of Drawing (4)	
<input type="checkbox"/>	PCT Declaration	
<input checked="" type="checkbox"/>	PCT Documents	
<input checked="" type="checkbox"/>	International Search Report	
<input checked="" type="checkbox"/>	Preliminary Amendment	
<input type="checkbox"/>	Assignment	
<input checked="" type="checkbox"/>	PTO-2038 for Official Fees	
<input checked="" type="checkbox"/>	Basic Fee (Large Entity)	\$1040.00
<input checked="" type="checkbox"/>	1 ind. claims in excess of 3	\$84.00
<input type="checkbox"/>	Claim in excess of 20	\$00.00
	Total	\$1124.00

Please charge any fees not covered by an enclosed PTO-2038 to account 18-2025 of the undersigned.

30 October 2001

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22054

IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor Harald GENGGER et al
Patent App. Not known (US Nat'l phase of PCT/EP00/03997)
Filed Concurrently herewith
For DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN
THE FOREHEAD AREA OF A PATIENT
Art Unit Not known
Hon. Commissioner of Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application,
please amend as follows:

In the Claims:

Claim 3, line 1, delete "or claim 2",

Claim 4, line 1, delete "one of claims 1 through 3",
insert instead -- claim 1 --,

Claim 5, line 1, delete "one of claims 1 through 4",
insert instead -- claim 1 --,

Claim 6, line 1, delete "one of claims 1 through 5",
insert instead -- claim 1 --,

Claim 7, line 1, delete "one of claims 1 through 6",
insert instead -- claim 1 --,

Claim 8, line 1, delete "one of claims 1 through 7",
insert instead -- claim 1 --,

Claim 9, line 1, delete "one of claims 1 through 8",
insert instead -- claim 1 --,

Claim 10, line 1, delete "one of claims 1 through 9",
insert instead -- claim 1 --,

Claim 11, line 1, delete "one of claims 1 through 10",
insert instead -- claim 1 --,

Claim 13, line 1, delete "one of claims 1 through 12",
insert instead -- claim 1 --,

Claim 14, line 1, delete "one of claims 1 through 13",
insert instead -- claim 1 --,

Claim 15, line 1, delete "one of claims 1 through 14",
insert instead -- claim 1 --,

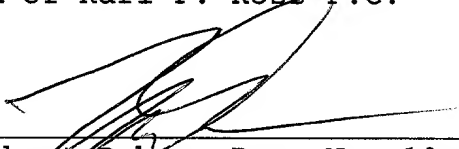
Claim 16, line 1, delete "one of claims 1 through 15",
insert instead -- claim 1 --,

Claim 18, line 1, delete "one of claims 1 through 17",
insert instead -- claim 17 --,

Claim 20, line 1, delete "one of claims 1 through 19",
insert instead -- claim 19 --.

This preliminary amendment is submitted just to reduce claim charges.

Respectfully submitted,
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4/pstb

4th May 2000

TEXT FILED

Description

Device for detecting electrical potentials in the forehead region of a patient

The invention concerns a device for detecting electrical potentials in the forehead region of a patient.

It is possible, on the basis of electrical potentials of that kind, to draw conclusions about the brain activity of a human being. In particular, it is possible, in the case of a person who is asleep, to determine the individual sleep states, on the basis of the brain activity which is ascertained during sleep.

German patent application DE 1 99 20 433.0 to the present applicants describes a CPAP device system in which the characteristic of the respiration gas feed is varied in dependence on the sleep state of the patient. For that purpose, the required electrodes are glued onto the forehead of the patient by way of an adhesive strip.

The correct application of such electrodes requires particular care and is frequently found to be unpleasant by the patient in question.

The object of the invention is to improve the reliability of detection of electrical potentials in the forehead region of a patient and to permit application of the required electrodes in a manner which is agreeable to the patient.

In accordance with the invention that object is attained by a device for detecting electrical potentials on a patient, with an electrode device which can be applied in the forehead region of the patient, wherein the electrode device is arranged on a forehead support element which co-operates with a breathing mask device in such a way that the application position of the electrode device is established in conjunction with the application position of the breathing mask device.

That makes it advantageously possible to apply the electrode device in the correct position, with a high level of reproduction accuracy.

In accordance with a particularly preferred embodiment of the invention the forehead support element is coupled to the breathing mask device. In that arrangement, the electrode device can advantageously be
5 directly applied to and removed from the breathing mask arrangement. It is possible to forego the adhesive strips which were hitherto required, which is an advantage.

A particularly high level of adaptability of the forehead support
10 element to the individual configuration of the forehead part of the patient and a high degree of wearing comfort is afforded, in accordance with a particularly preferred embodiment of the invention, by virtue of the forehead support element being formed from an elastomer material.

An embodiment of the invention which in particular saves weight
15 and which is advantageous from hygiene points of view is afforded if the forehead support element is formed in one piece with a mask base member of the breathing mask device.

In accordance with a particular aspect of the present invention the spatial configuration of the unit formed from the forehead support element
20 and the mask member can be adapted to the individual contour of the face of the patient by the provision of a stiffening element which stiffeningly couples together the forehead support element and the breathing mask device.

The electrode device preferably includes at least two electrode
25 elements, the potential difference being detected between those two electrode elements. Considerably more accurate determination of the electrical brain activity of the patient is made possible by the electrode device having at least three electrode elements. The electrode elements are placed for example in the frontal measurement locations fP1 and fP2
30 and a location therebetween. Preferably the measurement locations are

disposed in the forehead region of the patient about 30 mm above the eyebrows.

A particularly high level of measuring accuracy is advantageously achieved if the electrode elements are supported flexibly in a direction substantially perpendicular to the application face. That ensures that for example the arrangement does not give rise to electrode contact pressure forces which are different in dependence on a forehead band tension. For that purpose for example the electrode elements are accommodated in a cup structure. The flexible effect can be achieved by elastomer elements, in particular rolling bellow diaphragms. As an alternative thereto it is also possible for the electrode elements to be accommodated in a recess, the depth of the recess substantially corresponding to the thickness of the electrode elements.

In accordance with a particularly preferred embodiment of the invention the electrode elements are coupled to a signal processing device arranged in the immediate proximity of the electrode elements. For that purpose the signal processing device is particularly advantageously integrated into the forehead support element and has its own voltage supply device, for example in the form of a button cell. The output of the signal processing device is preferably potential-free and communicates directly with a data transmission device for cord-less and in particular radio transmission of the processed signals to a data processing device. It is possible for the potentials detected by way of the electrode elements also to be processed in the region of the forehead support element by means of a suitable data processing device so that a compressed or more informative data set is produced which can be forwarded at a lower level of transmission complication and expenditure. On the other hand it is also possible to forward substantially only the raw data, that is to say the measurement results, to a separate receiving device.

That receiving device can be part of a patient monitoring system of a sleep laboratory. It is also possible for the receiving device to be

integrated directly into a CPAP device. Particularly in the case of that embodiment, it is also possible, in place of telemetric signal transmission, to provide a data line which is particularly advantageously integrated into a breathing gas hose.

5 Particularly in regard to the area of use of sleep therapy for treating sleep-related respiratory disturbances the above-specified object is also attained by a breathing mask arrangement for feeding a respiration gas to a patient under an increased pressure, comprising a mask member which engages over the nose region of the patient, a sealing device for sealing
10 off an inner region of the mask with respect to the ambient atmosphere, and a forehead support element for supporting the mask member in the forehead region of the patient, characterized in that provided in the region of the forehead support element is an electrode device for detecting electrical and in particular brain-electrical potentials.

15 In that respect the forehead support element, as already described in greater detail hereinbefore, is also preferably formed from an elastomer material and is either produced integrally with the mask member or is coupled thereto in a defined manner by way of a suitable joining structure.

20 Particularly when the forehead support element and the mask member involve an integral design configuration, it is also formed from an elastomer material. Particularly in this embodiment, the forehead support element and the mask member are provided with stiffening or bracing means which extend into the forehead support element, the stiffening means preferably being adapted to the individual face contour of the
25 patient.

30 In combination with the above-described features or also alternatively thereto, the above-specified object is also attained by a device for detecting electrical potentials in the forehead region of a patient, in particular for determining sleep stages, comprising an electrode device, a measuring circuit arrangement for producing measurement data in accordance with the electrical potentials detected by the electrode

device, wherein the measuring circuit arrangement is integrated into a forehead support element, and there is provided a signal transmission device for cord-less transmission of the measurement data produced by the measuring circuit arrangement.

- 5 The measuring circuit arrangement preferably has a data compression device for transmitting a compressed data set to the signal transmission device.

10 In accordance with the invention, the foregoing object is attained in an advantageous fashion in accordance with a further aspect of the present invention by a device for detecting electrical potentials in the forehead region of a patient, in particular for determining sleep stages, comprising an electrode device, a measuring circuit arrangement for producing measurement data in accordance with the electrical potentials detected by the electrode device, wherein the measuring circuit
15 arrangement is integrated into a forehead support element, and there is provided a measurement data recording device for recording the measurement data produced by the measuring circuit arrangement.

20 In a particularly advantageous manner that measurement data recording device includes an approximately postage stamp-size memory card element which is releasably coupled to the forehead support element and which can be removed for example from the forehead support element for further processing of the recorded items of information. The measurement data can possibly be compressed by a compression device provided in the region of the forehead support element.

- 25 Further advantageous configurations of the invention are set forth in the appendant claims.

30 Further details will be apparent from the description hereinafter of a number of preferred embodiments of the invention and detail structures which are advantageously embodied in that respect, with reference to the accompanying drawing in which:

Figure 1 shows a perspective view of a breathing mask with a forehead support element which has three electrodes for detecting electrical potentials in the forehead region of the patient,

Figure 2 shows a simplified sectional view to illustrate an elastically
5 yielding mounting of an electrode element,

Figure 3a shows a perspective view of an elastomer band element which has three electrodes for detecting the electrical brain activity of a patient, wherein the band element can be coupled to a forehead support element,

10 Figure 3b shows a simplified sectional view through a forehead support element into which the band element shown in Figure 3a is fitted,

Figure 3c shows a simplified sectional view through an electrode element as is used in particular in the forehead support element shown in Figure 3a,

15 Figure 4 shows a perspective view of a further embodiment of a forehead support element with integrated electrode elements for detecting the electrical brain activity of a patient, wherein the forehead support element can be coupled to a duct portion of a breathing mask,

Figure 5 shows a simplified view to illustrate a forehead band
20 element with integrated signal processing device,

Figure 6a shows a perspective view of a signal processing device provided for use in a forehead support element, either in case a for telemetric data transmission (for example by radio) or case b for the storage of a preferably compressed data set on an interchangeable data
25 carrier, preferably in chip card form,

Figure 6b shows a simplified sectional view through a receiving portion in a forehead support element for receiving the signal processing device shown in Figure 6a, and

Figure 7 shows a simplified view of a measuring arrangement
30 according to the invention for detecting the electrical brain activity of a

patient here with a total of five electrode elements pre-positioned by way of a breathing mask and a telemetric data transmission device.

The breathing mask shown in Figure 1 includes a mask member 1 which delimits an internal space 2 of the mask. Provided on an edge portion which is towards the ambient region of the nose of a patient is a sealing device 3 which here has at least one elastic sealing lip which comes into intimate contact with the surface of the face of the patient and in so doing seals off the internal space 2 of the mask with respect to the ambient atmosphere. Here, the sealing device 3 has a portion 4 which is drawn in comparatively deeply in the region of the bridge of the nose, thereby affording placement of the mask member 1 with respect to the nose of the patient, in such a way that it remains the same with a high degree of accuracy of repetition.

In the embodiment illustrated here the mask member 1 has a breathing gas duct 5 which extends through a forehead support element 6. In the embodiment illustrated here, the mask member 1 and the forehead support element 6 are formed integrally from an elastomer material, in particular a fully transparent silicone rubber material.

In the illustrated embodiment, the forehead support element 6 is provided with connecting members 7 by way of which the forehead support element 6 can be coupled to a preferably cushioned forehead band. In the illustrated embodiment, the contact surface 8 of the forehead support element 6, which faces towards the forehead of the patient, is of a slightly concave configuration and in addition is adapted by a stiffening element (not shown here) to the individual contour of the forehead region of the patient, in terms of the curvature thereof. In the illustrated embodiment arranged in the contact surface 8 are a total of three electrode elements 9, 10 and 11, by way of which it is possible to detect electrical potentials in the forehead region of the patient.

The position of the electrode elements 9, 10, 11 relative to the patient can be maintained with high level of accuracy of repetition as the

unit formed by the mask member 1 and the forehead support element 6 is fixed precisely, in particular by the nose region of the patient.

In the embodiment illustrated here, the breathing gas duct 5 is of a non-round and in particular polygonal cross-section and in addition is of a configuration such as to curve towards the patient, corresponding to the curvature of the forehead of the patient. The cross-sectional shape used here provides that the breathing gas flows into the internal space 2 of the mask in a substantially eddy-free flow. That measure represents an independent novel structural configuration of the invention for improving the breathing gas flow which can also be implemented on its own account, independently of the features otherwise described herein.

Referring to Figure 2, shown therein is a simplified diagrammatic view illustrating a preferred embodiment of the mounting of the electrode elements 9, 10, 11 as are used in the breathing mask shown in Figure 1. As can be seen, the electrode elements 9, 10, 11 are formed by a thin metal plate 12 which is mounted yieldingly substantially perpendicularly to the contact surface 8. The yielding mounting is achieved in this case by a diaphragm structure which is formed integrally with the forehead support element 6. Provided in the rearward region of the metal plate 12 is a highly flexible metal line device 14 which will be described hereinafter in an embodiment which is described in greater detail with reference to Figures 3a and 5. The elastically yielding mounting for the electrode elements 9, 10 and 11 as shown in Figure 2, provides that the electrode elements are urged against the surface of the skin of the patient with a contact pressure force which remains substantially the same, thereby avoiding possibly falsified measurement results as a consequence of different forces in the forehead band arrangement.

Figure 3b shows a particular embodiment of the electrode arrangement according to the invention, which here has a band 15 which is formed from an elastomer material and into which the electrode elements 9, 10 and 11 are fitted. The band 15 is of an outside contour

which permits positionally accurate coupling to a forehead support element. Fitted in an end portion of the band 15 is a signal processing device 16 which is connected by way of thin connecting lines 14, 17 and 18 to the respective electrode elements 9, 10 and 11.

5 The potential differences between the respective electrode elements are detected and evaluated in that signal processing device. The measurement data obtained in that way are either stored in suitably encoded form or passed by telemetric means to a receiving device for further data processing.

10 Figure 3c is a sectional view through a portion of a forehead support element 6 into which is fitted the band 15 referred to in reference to Figure 3a. For that purpose a recess 19 is provided in the forehead support element 6. The depth of the recess 19, which is set back with respect to the contact surface 8, is such that the contact surface 20
15 formed by the band 15 terminates substantially flush with the contact surface 8.

 The electrode elements 9, 10 and 11 are mounted on the band 15, as already indicated in Figure 3a.

20 As indicated in Figure 3b for example the electrode elements can be fixed by the electrode elements having on their rear side needle-like projections 21, by way of which the electrode elements can be individually placed on the band 15 or directly on the forehead support element 6.

 As an alternative thereto it is also possible to form shallow recesses in the forehead support element 6 or in the band 15. The shallow
25 recesses are delimited by a peripheral edge into which the electrode elements 9, 10 and 11 can be clipped, by means of a slight clipping fit.

 Figure 4 shows a perspective view of a forehead support element 6 which can be coupled to a breathing gas duct portion of a breathing mask. For that purpose the forehead support element 6 has a mask fixing portion
30 22. The mask fixing portion, in the embodiment illustrated here, includes

a flexible band 23 defining a through passage 24 for receiving the breathing gas duct 5.

The forehead support element 6 also has connecting members 7 which - as already indicated with reference to Figure 1 - serve for the further connection of a forehead band. The electrode elements 9, 10 and 11 are again fitted in the region of the contact surface 8 of the forehead support element 6. The electrode elements 9, 10 and 11 can be repeatedly applied in an accurate position in the forehead region of the corresponding patient, as a consequence of the breathing mask being coupled to the forehead support element 6.

Figure 5 indicates in a simplified manner the fashion in which the individual electrode elements 9, 10 and 11 are coupled to the signal processing device 16 by way of the connecting lines 14, 17 and 18. In this case, the signal processing device 16 includes a directly connected data transmission device 24 by way of which the measurement data obtained can be cord-lessly forwarded to a suitable system for further processing. In the embodiment illustrated here, all of the specified components are sealingly embedded in the base member of the forehead support element 6, the base member being formed from an elastomer material.

Figure 6a shows a particularly preferred embodiment of the signal processing device 16 which is here accommodated in an outer casing 25 and has a plurality of contact elements 26, 27 and 28 which can be electrically connected to the connecting lines 14, 17 and 18 referred to in connection with Figure 5. The processing device 16 illustrated here includes its own voltage supply device formed by a button cell (not shown) and, in dependence on the potential differences detected between the contacts elements 26, 27 and 28, produces binary-coded data. Those data can be transmitted to an external data processing system, as indicated for case a, in the form of electromagnetic waves, in particular by radio. As an alternative thereto or also in combination therewith, it is

possible - as indicated for case b - for the measurement data obtained to be stored on a data carrier 29. In order to obtain direct association in respect of time of said measurement data, the signal processing device 16, in accordance with a particularly preferred embodiment of the invention, can be provided with a clock so that the measurement data produced are also stored in accordance with an association in respect of time.

The signal processing device 16 which is in the form of a completely self-contained block can be clipped - as indicated in Figure 6b - into a recess 30 which is clipped directly in the forehead support element 6 or as indicated for example in the case shown in Figure 3a into a suitable band 15. In that case, by virtue of the inherent elasticity of the material surrounding the recess 30, the contact elements 26, 27 and 28 on the signal processing device 16 come into a sufficiently high pressing contact relationship with the further co-operating contacts 31 provided in the forehead support element 6. Those co-operating contacts 31 are connected to the above-mentioned signal lines 14, 17 and 18.

Figure 7 shows in a simplified fashion the way in which a breathing mask according to the invention with integrated forehead electrodes is applied in the face region of a patient. It will be clear in that respect that extremely precise positioning of the electrode elements is achieved by virtue of the coupling in accordance with the invention of the electrode elements to a forehead support element which is provided to support a breathing mask. That arrangement makes it possible for a plurality of electrode elements, in particular as shown here five electrode elements, to be applied in the forehead region of the patient, in which case upon fresh application of the electrode elements substantially the same measurement position is again employed as in the case of the preceding measurement procedures. That provides for considerably improved comparability of the data obtained in the context of different measurement cycles.

The measuring arrangement shown in Figure 7 includes the mask member 1 and the forehead support element 6 which is coupled thereto by way of the breathing gas duct portion 5 and which is only indicated here. Arranged in the forehead support element 6 in this case are a total
5 of five electrodes 9, 10, 11 and 33 and 34 by way of which it is possible to detect electrical potential differences in the forehead region of the patient.

The potential differences detected in that way are evaluated by the signal processing device 16 integrated in the forehead support element 6 and forwarded by way of radio signals to an external receiving device for
10 further processing and in particular for the control of a CPAP unit.

In this case, the feed of respiration gas to the internal space of the mask, which is defined by the mask member 1, is by way of a breathing gas hose 35 provided with a reinforcing insert of spiral configuration.

Particularly in the case of a breathing gas hose of that kind, it is
15 possible to provide that the signals are transmitted by means of a line device which is integrated into the breathing gas hose 35, in particular in the spiral reinforcing member thereof, instead of the signals produced by the signal processing device 16 being transmitted by way of radio.

The region of the mask member which is adjacent to the mouth of
20 the patient, is urged against the face of the patient with a predetermined contact pressure force, by a lower webbing band arrangement 36. The forehead support element 6 is urged against the forehead of the patient with an adjustable contact pressure force by an upper webbing band arrangement 37 which extends around the region of the back of the head
25 of the patient. Both the lower band arrangement 36 and also the upper band arrangement 37 in the embodiment illustrated here are formed by a cushioned band material which is comparatively resistant to tensile force. The high level of resistance to tensile force of that band material provides that, even when the breathing mask is applied to the face of the patient
30 with comparatively low levels of contact pressure force, the breathing mask does not lift away from the face of the patient, as a consequence of

CLAIMS

1. A device for detecting electrical potentials on a patient, with an electrode device which can be applied in the forehead region of the patient, wherein the electrode device is arranged on a forehead support element which co-operates with a breathing mask device in such a way that the application position of the electrode device is established in conjunction with the application position of the breathing mask device.

2. A device as set forth in claim 1 characterized in that the forehead support element is coupled to the breathing mask device.

3. A device as set forth in claim 1 or claim 2 characterized in that the forehead support element is formed from an elastomer material.

4. A device as set forth in one of claims 1 through 3 characterized in that the forehead support element is formed in one piece with a mask base member of the breathing mask device.

5. A device as set forth in one of claims 1 through 4 characterized in that there is provided a stiffening element which stiffeningly couples together the forehead support element and the breathing mask device.

6. A device as set forth in one of claims 1 through 5 characterized in that the electrode device has at least two electrode elements.

7. A device as set forth in one of claims 1 through 6 characterized in that the electrode device has three electrode elements.

8. A device as set forth in one of claims 1 through 7 characterized in that electrode elements are mounted into an application surface yielding in a substantially perpendicular direction.

9. A device as set forth in one of claims 1 through 8 characterized in that the electrode elements are coupled to a signal processing device.

10. A device as set forth in one of claims 1 through 9 characterized in that the signal processing device is integrated into the forehead support element.

11. A device as set forth in one of claims 1 through 10 characterized in that the signal processing device is provided with a data transmission device for the cord-less transmission of the processed signals to a data processing device.

12. A breathing mask arrangement for feeding a respiration gas to a patient under an increased pressure, comprising:

- a mask member which engages over the nose region of the patient,
- a sealing device for sealing off an inner region of the mask with respect to the ambient atmosphere, and
- a forehead support element for supporting the mask member in the forehead region of the patient, characterized in that provided in the region of the forehead support element is an electrode device for detecting electrical and in particular brain-electrical potentials.

13. A device as set forth in one of claims 1 through 12 characterized in that the forehead support element is formed from an elastomer material.

14. A device as set forth in one of claims 1 through 13 characterized in that the mask member is formed from an elastomer material.

15. A device as set forth in one of claims 1 through 14 characterized in that the forehead support element and the mask member are integral.

16. A device as set forth in one of claims 1 through 15 characterized in that the mask member and the forehead support element are adapted to the individual contour of the face of the patient by virtue of stiffening with a stiffening device which extends into the forehead support element.

17. A device for detecting electrical potentials in the forehead region of a patient, in particular for determining sleep stages, comprising:

an electrode device, a measuring circuit arrangement for producing measurement data in accordance with the electrical potentials detected by the electrode device, characterized in that the measuring circuit arrangement is integrated into a forehead support element, and there is provided a signal transmission device for cord-less transmission of the measurement data produced by the measuring circuit arrangement.

18. A device as set forth in one of claims 1 through 17 characterized in that the measuring circuit arrangement has a data compression device for forwarding a compressed data set to the signal transmission device.

19. A device for detecting electrical potentials in the forehead region of a patient, in particular for determining sleep stages, comprising:

an electrode device, a measuring circuit arrangement for producing measurement data in accordance with the electrical potentials detected by the electrode device, characterized in that the measuring circuit arrangement is integrated into a forehead support element, and there is provided a measurement data recording device for recording the measurement data produced by the measuring circuit arrangement.

20. A device as set forth in one of claims 1 through 19 characterized in that the measurement data recording device is formed by an approximately postage stamp-size memory card element which is releasably fitted.

PCT

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INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE
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SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG,
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(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches
Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR,
IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht

Mit internationalem Recherchenbericht.

Vor Ablauf der für Änderungen der Ansprüche zugelassenen
Frist; Veröffentlichung wird wiederholt falls Änderungen
eintreffen.

(54) Title: DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN THE FOREHEAD-AREA OF A PATIENT

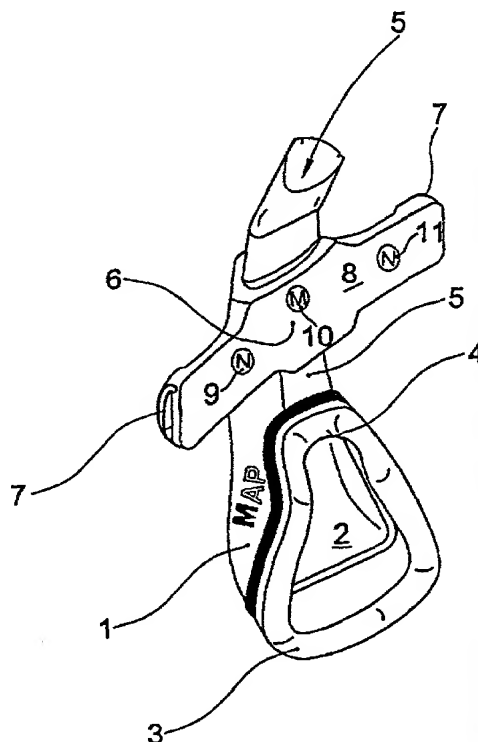
(54) Bezeichnung: VORRICHTUNG ZUR ERFASSUNG ELEKTRISCHER POTENTIALE IM STIRNBEREICH EINES PATIENTEN

(57) Abstract

The invention relates to a device for detecting electrical potentials on a patient. The device comprises an electrode device that is applied in the area of the forehead, this electrode device being located on a forehead support element (6) which is connected to a breathing mask (1). The electrode device preferably comprises at least two electrode elements (9, 10, 11). According to a preferred embodiment of the invention, these electrode elements are connected to a signal processing device which is located in the direct proximity of the electrode elements. The output of said signal processing device is preferably potential-free and communicates directly with a data transmission device, so that the processed signals can be transmitted to a data processing device in a cordless manner, especially by radio transmission. The invention can be used in a patient monitoring system of a sleep laboratory or in a CPAP device.

(57) Zusammenfassung

Die Erfindung betrifft eine Vorrichtung zur Erfassung elektrischer Potentiale an einem Patienten mit einer im Stirnbereich applizierbaren Elektroden-einrichtung, wobei die Elektroden-einrichtung an einem Stirnauflageelement (6) angeordnet ist, das mit einer Atemmaske (1) gekoppelt ist. Die Elektroden-einrichtung umfasst vorzugsweise wenigstens zwei Elektroden-elemente (9, 10, 11). Die Elektroden-elemente sind gemäss einer bevorzugten Ausführungsform der Erfindung mit einer Signalverarbeitungseinrichtung gekoppelt, die in unmittelbarer Nähe der Elektroden-elemente angeordnet ist. Der Ausgang der Signalverarbeitungseinrichtung ist vorzugsweise potentialfrei und kommuniziert unmittelbar mit einer Datenübertragungseinrichtung, zur schnurlosen insbesondere Funk-Übertragung der verarbeiteten Signale an eine Datenverarbeitungseinrichtung. Die Erfindung kann in einem Patientenüberwachungssystem eines Schlaflabors oder in einem CPAP-Gerät angewendet werden.



22054

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: My residence, post-office address, and citizenship are as stated below next to my name,
I believe that I am an original joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN THE FOREHEAD AREA OF A PATIENT

the specification of which was filed on 4 May 2000 as PCT application PCT/EP00/03997.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 USC 119 of any foreign applications for patent or inventor's certificate listed below and have also identified below any foreign applications for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Applications

Country	Number	Filing Date	Priority claimed
DE	19920433.0	4 May 1999	Yes
DE	19936505.9	5 August 1999	Yes
DE	29917806.4	8 October 1999	Yes
DE	19956841.3	26 November 1999	Yes

I hereby claim the benefit under 35 USC 120 of the United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States Application(s) in the manner provided by the first paragraph of 35 USC 112, I acknowledge the duty to disclose material information as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Serial Number	Filing Date	Status
PCT/EP00/03997	4 May 2000	Pending

I hereby appoint as attorneys to prosecute this application and to transact all business connected therewith: **Herbert Dubno, Reg. 19,752; Jonathan Myers, Reg. 26,963; Andrew Wilford, Reg. 26,597** and each of them individually.

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**The Firm of Karl F. Ross, P.C.
Customer Number 535**

**5676 Riverdale Avenue, Box 900
Bronx, New York 10471-0900**

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: My residence, post-office address, and citizenship are as stated below next to my name,
I believe that I am an original joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

DEVICE FOR DETECTING ELECTRICAL POTENTIALS IN THE FOREHEAD AREA OF A PATIENT

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both, under 18 USC 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

100 Full name of first inventor: Harald Genger
Inventor's signature [Signature] Date: 29/11/01
Residence: Starnberg, Germany DER Citizen of Germany
Post-office Address: Wildmoosstrasse 11, D-82319 Starnberg, Germany

Full name of second inventor: Claus NEGELE
Inventor's signature _____ Date: _____
Residence: München, Germany Citizen of Germany
Post-office Address: Hohenzollernstrasse 50, D-80801 München, Germany

22054

Ser. No. Not known - US phase of PCT/EP00/03997

both, under 18 USC 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor:

Harald Genger

Inventor's signature _____ Date: _____

Residence: **Starnberg, Germany**

Citizen of Germany

Post-office Address: **Wildmoosstrasse 11, D-82319 Starnberg, Germany**

2-00
Full name of second inventor:

Claus NEGELE

Inventor's signature C. Negele Date: 17.12.01

Residence: **München, Germany** *DEX*

Citizen of Germany

Post-office Address: **Hohenzollernstrasse 50, D-80801 München, Germany**

1/4

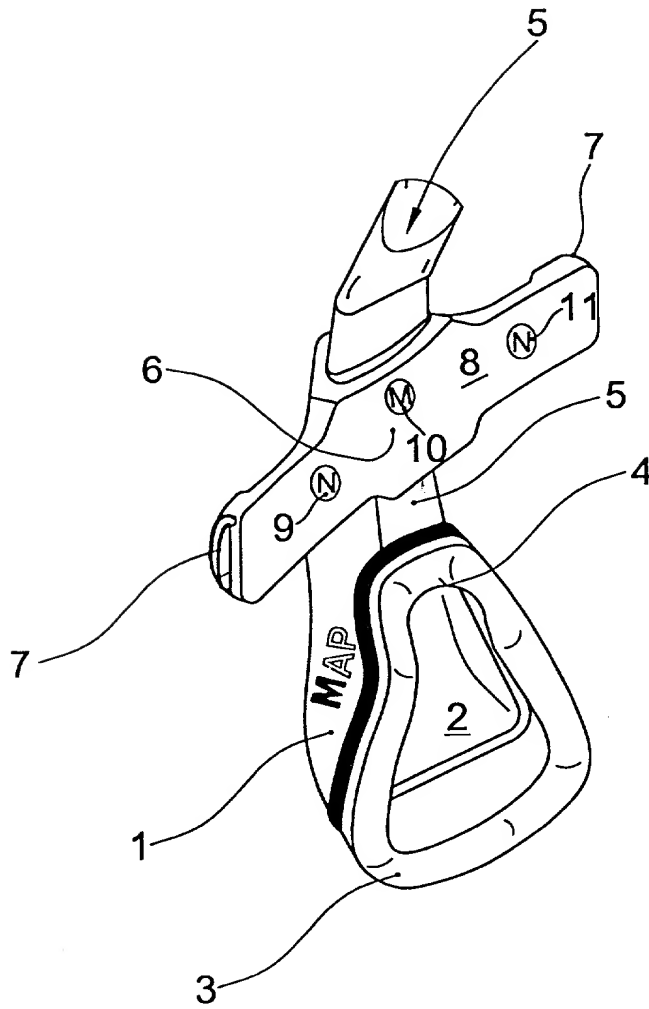


Fig.1

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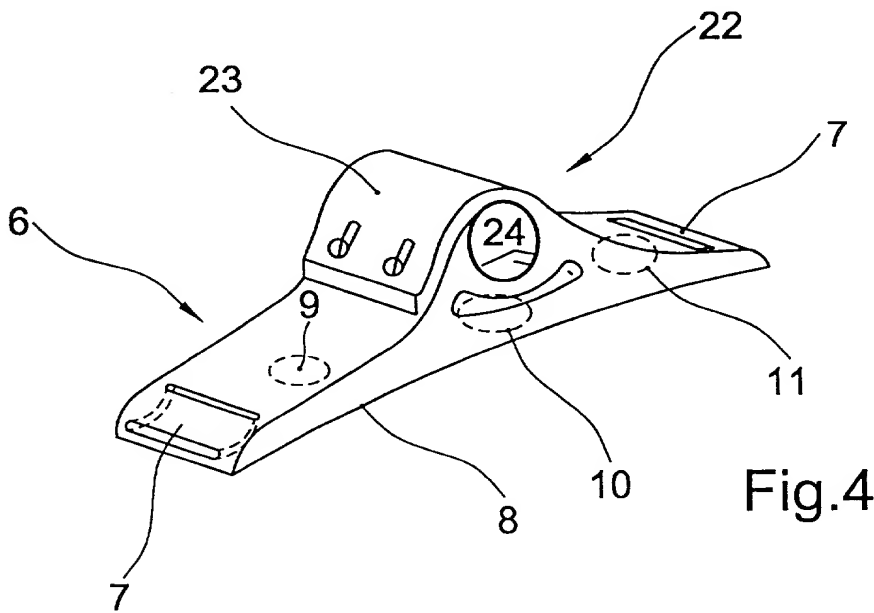
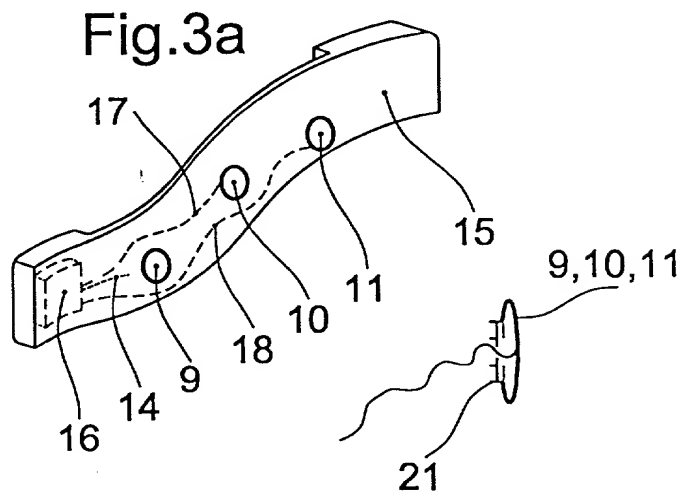
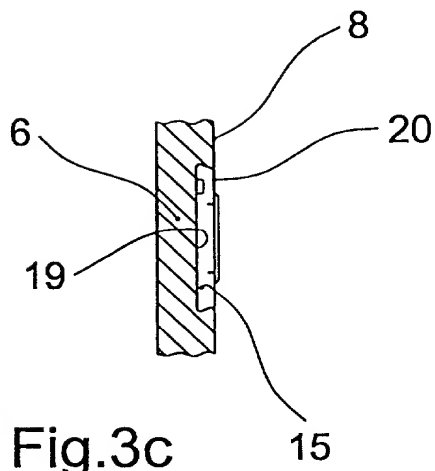
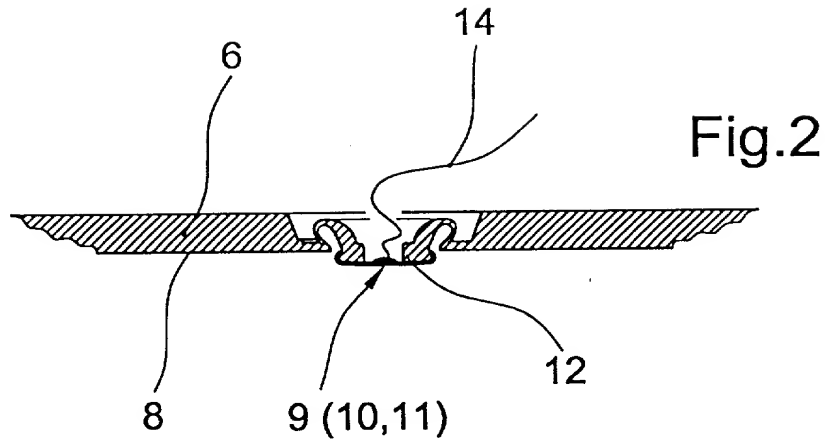


Fig.5

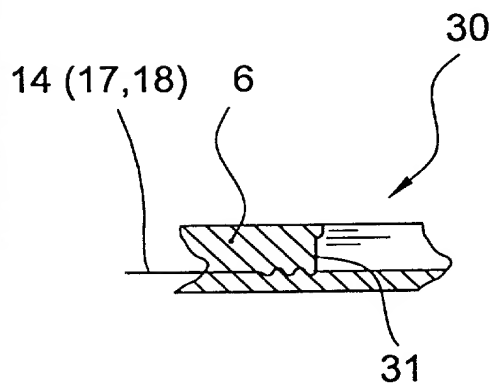
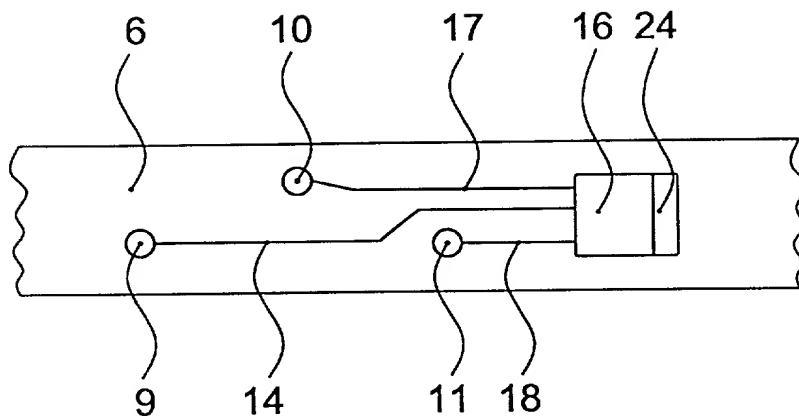


Fig.6b

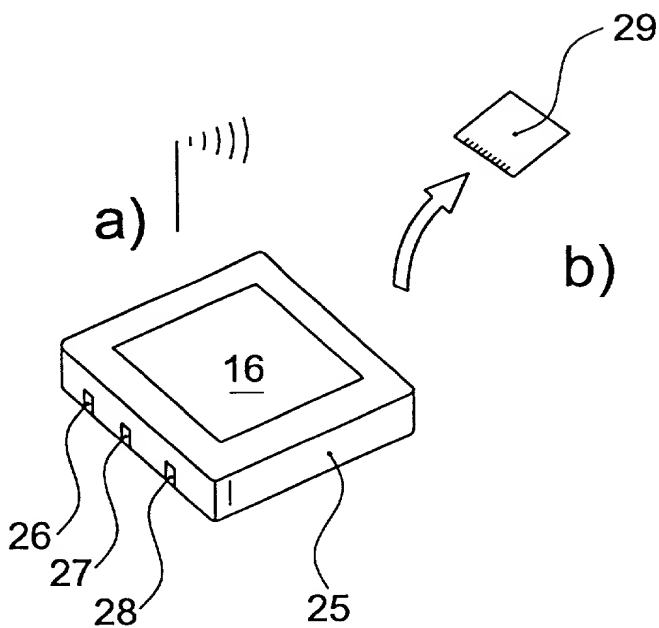


Fig.6a

